

## SUMMARY OF SAFETY AND EFFECTIVENESS

K963135

### 1. Name of Manufacturer

TechLab, Inc.  
1861 Pratt Drive  
Corporate Research Center  
Blacksburg, VA 24060

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### 2. Establishment Registration

Federal ID # 54-1527427  
Initial Registration of Medical Device Establishment, #1122855

### 3. Trade Name

*Giardia* CELISA

### 4. Common Name

*Giardia* enzyme immunoassay

### 5. Class of Device

This device is classified in Class I.

### 6. Performance Standards

No performance standards have been developed for this device under 514 of the Food, Drug, and Cosmetic Act.

### 7. Safety and Effectiveness

The *Giardia* CELISA can be used to detect *Giardia* cysts in fecal specimens from persons suspected of having giardiasis. The kit, which includes ready-to-use reagents, contains microtiter wells coated with monoclonal antibody, positive control reagent, detecting antibody (polyclonal antibody), conjugate (anti-rabbit IgG-peroxidase), substrate, wash solution, and intensifier. The microtiter wells coated with monoclonal antibody "capture" the antigen and the polyclonal antibody serves as the "detecting" antibody. The polyclonal antibody used as the detecting antibody is prepared from hyperimmune antiserum developed in rabbits. The monoclonal antibody used to coat microtiter wells is prepared from mouse ascites fluid.

The *Giardia* CELISA is to be used in an enzyme immunoassay format and is substantially equivalent to microscopy (conventional staining methods) used in some clinical laboratories as diagnostic aids for giardiasis. In addition, the *Giardia* CELISA is substantially equivalent to the Meridian Premier *Giardia lamblia* which has been approved for *in vitro* diagnostic use. These tests all serve as diagnostic aids for *Giardia*-associated disease by detecting the organism or its antigens.

The *Giardia* CELISA was compared with the detection of the organism in fecal specimens by microscopy with conventional staining. In addition, the test was compared with the Meridian Premier *Giardia lamblia* for the detection of *Giardia* antigen in fecal specimens. The results of our clinical evaluations show that the *Giardia* CELISA exhibits a correlation of >95% when compared with these other methods for detecting *Giardia* in fecal specimens. These results show that the *Giardia* CELISA is useful for the detection of *Giardia* in fecal specimens.